DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

July 17, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 27

David H. Ohman, DVM
Owner
Dairy Production Services
N 5157 Kettle Moraine Drive
Glenbeulah, Wisconsin 53023

Dear Dr. Ohman:

On May 7 and 13, 2003, an investigator from the Food and Drug Administration (FDA) conducted an investigation into an illegal tissue residue in a dairy cow sold for slaughter as human food by ~~~~~~~~~~~~~~~~~~That investigation included a review of your involvement with the aforementioned residue. The investigation revealed serious deviations from the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations (C.F.R.), Part 530. These deviations caused an animal drug to be used in a manner that was unsafe under Section 512(a) of the Federal Food, Drug and Cosmetic Act (the Act) and adulterated within the meaning of Section 501(a)(5) of the Act. The investigation also revealed that you caused an animal drug to be misbranded within the meaning of Section 502(f)(1) of the Act.

On or about March 13, 2003, ~~~~~ offered a dairy cow (ear tag number 2851) for slaughter as human food to ~~~~~~~~~~~~ ~~~~ U.S. Department of Agriculture (USDA) analysis of tissue samples collected from this cow (backtag 35 HWO 158) identified the presence of flunixin at 3.70 ppm in the liver. A tolerance of 0.125 ppm has been established for residues in cattle liver, 21 C.F.R. § 556.286.

Flunixin is not approved for use in lactating or dry dairy cows per 21 C.F.R. § 522.970. However, the extralabel use of approved veterinary or human drugs is permitted if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and

21 C.F.R. Part 530. Our investigation found that you failed to comply with 21 C.F.R. Part 530 in that:

- You failed to make a careful diagnosis and evaluation of the conditions for which the drug was to be used prior to prescribing or dispensing the drug for extralabel use, as required by 21 C.F.R. § 530.20(a)(2)(i).

- You failed to take appropriate measures to assure that no illegal drug residues occur in a food-producing animal prior to prescribing or dispensing the drug for extralabel use, as required by 21 C.F.R. § 530.20(a)(2)(iv).

- The labeling for the drug you prescribed and that was dispensed by or on your order failed to contain information required by 21 C.F.R. § 530.12. For example, the labeling did not contain directions for use per 21 C.F.R. § 530.12(c) or withdrawal, withholding, or discard time per 21 C.F.R. § 530.12(e).

- The resulting extralabel use of flunixin caused an illegal drug residue. 21 C.F.R. § 530.11(d) prohibits any extralabel use that results in a residue above an established tolerance.

Because you failed to comply with the requirements of 21 CFR Part 530 in dispensing an animal drug, your customer used new animal drugs in an unapproved manner without meeting the requirements for extralabel use set forth in Section 512(a)(4)(A) and 21 C.F.R. Part 530, thereby rendering the drugs unsafe under Section 512 of the Act and adulterated under Section 501(a)(5) of the Act.

In addition, you caused the drug to be misbranded within the meaning of Section 502(f)(1) of the Act in that it was dispensed for extralabel use, within the meaning of 21 C.F.R. § 530.3(a), and without the labeling required by 21 C.F.R. § 530.12.

It is not necessary for you to personally ship an adulterated or misbranded drug in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration or misbranding of a drug that was sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a licensed veterinarian, you are responsible for complying with the requirements of the Act, including the extralabel use regulations promulgated under the Act. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

We have enclosed a copy of 21 C.F.R. Part 530 for your reference. We strongly suggest that you review 21 C.F.R. Part 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TGP/ccl

Enclosure: 21 C.F.R. Part 530

xc: Robert Ehlenfeldt, DVM
Acting State Veterinarian
Wisconsin Department of Agriculture,
Trade and Consumer Protection
Division of Animal Health
P.O. Box 8911
Madison, WI 53708-8911

Cathy Pond
Division Administrator
Wisconsin Department of Regulation
and Licensing
P.O. Box 8935
Madison, WI 53708-8935